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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,658	03/20/2001	Chieko Kitada	2549US0P	4776

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TAKEDA PHARMACEUTICALS NORTH AMERICA, INC
INTELLECTUAL PROPERTY DEPARTMENT
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LINCOLNSHIRE, IL 60069

EXAMINER

LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 01/28/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/787,658

Applicant(s)

KITADA ET AL.

Examin r

Robert Landsman

Art Unit

1647

-- The MAILING DATE of this communicati n appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-28 is/are rejected.
- 7) ☒ Claim(s) 1-28 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 March 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5. 6) ☐ Other: _____

DETAILED ACTION

1. Formal Matters

- A. The Information Disclosure Statement, filed 3/20/01, has been entered into the record.
- B. Claims 1-28 are pending and were subject to restriction in Paper No. 6, filed 10/07/02. In Paper No. 7, filed 11/1/02, Applicants elected SEQ ID NO:33, with traverse. Applicants argue that the scope of the peptides encompassed by the present invention are sufficiently related so not to unduly burden the Examiner. This argument has been considered, and the Examiner has reconsidered the restriction requirement. Therefore, the Examiner will search the following sequences: SEQ ID NO:3-21 and 25-40.

2. Bibliographic Data Sheet

- A. The foreign application, JP 10/271626, appears to have been filed 9/25/98. However, the Bibliographic Data Sheet (i.e. Filing Receipt) shows this foreign application was filed 9/25/99. Applicants can either request a corrected filing receipt, or one will be provided if this application is in condition for allowance.

3. Title

- A. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

4. Specification

- A. The specification is objected to since the priority data is not present in the first line of the specification. The first line of the specification should state that this application is a 371 of PCT/JP99/05216.

5. Claim Objections

- A. SEQ ID NO:3-21 and 25-40 are free of the art. However, claims 1-28 are objected to since they recite non-elected SEQ ID NOs. It is suggested that the claims be rewritten to recite only these SEQ ID NOs.

Art Unit: 1647

6. Claim Rejections - 35 USC § 112, first paragraph - enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

A. Claims 26-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

First, the breadth of the claims is excessive since the claims read on all pharmaceutical compositions to treat all diseases. Applicants have not recited the use of this composition to suppress any disease. Furthermore, Applicants have provided no guidance or working examples of any methods of treatment for any diseases using these peptides, including any data or treatment regimen. Furthermore, it is not predictable to one of ordinary skill in the art how to use a pharmaceutical composition. Applicants can overcome this rejection by amending the claims to recite, for example, "A composition comprising the peptide of SEQ ID NO:...and an inert carrier."

In summary, the breadth of the claims is excessive with regard to Applicants claiming pharmaceutical compositions. There is also a lack of guidance and working examples of the diseases to be treated as well as how to use these compositions to treat diseases. These factors, along with the lack of predictability to one of ordinary skill in the art as to how to use pharmaceutical compositions comprising these peptides, would lead the Examiner to hold that undue experimentation is necessary to practice the invention as claimed.

Art Unit: 1647

7. Claim Rejections - 35 USC § 112, first paragraph – written description

A. Claims 26-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants have not provided adequate written description of pharmaceutical compositions in the specification. No description of any diseases or use of these compositions has been described in the specification. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the diseases or how to use the peptides of the invention, one of skill in the art would reasonable conclude that the Applicant was not in possession of the claimed genus at the time the invention was made.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
January 27, 2003

